

Medical futility and the Texas Advance Directives Act of 1999

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CME

ETHICS CME, Part 1 of 3

Target audience: All physicians

Learning objectives:

1. Explore various definitions and the history of medical futility
2. Examine important court rulings
3. Review the new Texas Advance Directives Act as it applies to medical futility
4. Reflect on cultural changes necessary to deal with the concept of medical futility

Faculty credentials/disclosure:

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Before beginning this activity, please read the instructions for CME on p. 201. This page also provides important information on method of physician participation, estimated time to complete the educational activity, medium used for instruction, date of release, and expiration. The quiz, evaluation form, and certification appear on pp. 201–203 as well.

A new law regulating many decisions related to end-of-life care in Texas went into effect on September 1, 1999. Members of the Baylor University Medical Center Institutional Ethics Committee were instrumental in developing this new statute, which in many ways is groundbreaking and unique.

The purpose of this article is to examine how one part of this new law, that dealing with medical futility, impacts medical practice. The following case study illustrates both the problem of medical futility and the response required of physicians and institutions under the new law. The concept of medical futility is briefly explored, and the impact of the new law on the case study is analyzed.

CASE STUDY

An 82-year-old African American man who lived independently had been in relatively good health until he sustained a major stroke approximately 8 months before ethics consultation. After the stroke, which initially left him hemiparetic, he had been continuously institutionalized, moving between the acute care hospital, rehabilitation hospital, and nursing home.

The patient had had additional bilateral strokes, leaving him profoundly neurologically impaired. He was unable to control voluntary movements, bowel, or bladder. He was minimally responsive to voice and touch. He had diffuse contracture of all 4 extremities. The patient showed no clear evidence of joy in life but demonstrated that he felt pain by grimacing and moaning. He was unable to swallow well and suffered with recurrent aspiration. He had been transiently intubated for respiratory compromise, although he was off the ventilator at the time of the consult.

A percutaneous endoscopic gastrostomy for enteral alimentation had been placed. Because of recurrent malfunctions and complications, it had been replaced on numerous occasions. Even though efforts were made to maintain nutritional balance, the patient developed significant clinical and chemical markers for malnutrition.

The patient's neurologic problems were compounded by general debility and 2 large bilateral trochanteric decubiti, multiple smaller heel decubiti, and presacral decubiti acquired in the nursing home. These skin ulcers as well as chronic indwelling Foley catheters were believed to be the source of several recurrent bouts of gram-negative sepsis. The large trochanteric decubiti failed to respond to 2 months of intensive hospital-based treatment, and surgical consultants declined to operate on him in view of his profound frailty. Finally, he had heart failure and had several bouts of respiratory failure associated with aspiration.

Several times the physician caring for this patient had recommended that the family consider a do-not-resuscitate order as well as full withdrawal of treatment. She believed that both cardiopulmonary resuscitation (CPR) and ongoing treatment with enteral alimentation, antibiotics, and transfer back to the intensive care unit when he again deteriorated would be futile. However, her efforts to achieve consent for such a change of plans were rebuffed. The patient's wife of 3 years intimated that if no one else objected, she would authorize a switch to comfort care only. However, this wife did not have a good relationship with the patient's offspring from his first marriage, an adult daughter. The daughter demanded that "everything be done," including CPR, to try to save her father, arguing from a religious perspective that physicians must unconditionally treat him with

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all available medical therapy. At this point, the attending physician requested an ethics consult.

HISTORICAL BACKGROUND OF MEDICAL FUTILITY

The concept of medically futile treatment is as old as the Western medical tradition. In one of the ancient Hippocratic treatises, *The Art*, physicians and patients are admonished: "Whenever a man [sic] suffers from an illness, which is too strong for the means at the disposal of medicine, he surely must not expect that it can be overcome by medicine." The ancient Greek healers suggested that among the 3 goals of medicine were cure, relief of suffering, and the refusal to treat those "overmastered by their illness" (1). Patients were admonished not to ask healers to attempt that which was impossible to medicine. The text reminded physicians that to attempt a futile treatment was to display an ignorance that is "allied to madness."

These same ancient healers and philosophers, however, went on to note that "dreadful diseases demand dreadful remedies" (2). Throughout history, as medical science and practice have progressed, one generation's futile treatment becomes the next generation's bold experiment, which may go on to become efficacious therapy. Consider the rapid development of effective pharmacologic agents for a variety of previously untreatable illnesses (antibiotics for sepsis or insulin for diabetes), advanced surgical techniques, organ transplants, and technologic substitutes for failed organs (such as dialysis and mechanical ventilators). In 1960, the first successful reports of CPR defeating death (at least in some circumstances) were reported in the literature (3). When death no longer clearly represented an "illness too strong for the means at the disposal of medicine," it became difficult for the profession to determine the nature of futile medical treatments and thus difficult to decide if or when such treatments should be stopped because the patient was "overmastered."

Some families and patients, however, did not have such difficulty. By the mid 1970s, some families and patients argued that certain life-sustaining treatments should be stopped, as they no longer met the reasonable goals of the patient (one definition of futility). A number of these cases were played out in the judicial system. The first to catch the public's and profession's attention was that of Karen Quinlan. Still, these early cases of conflict between the healing profession and patients or their surrogates were not referred to as medical futility cases but instead as "right-to-die" cases. By the time of the Cruzan case (1984–1990), it was firmly established that patients had a clear right to refuse life-sustaining treatments (although states could regulate the process of refusal).

In the late 1980s, physicians started to assert that certain life-sustaining treatments should be withdrawn or withheld because they no longer met the legitimate goals of medicine and were thus "futile." In the 1988 *Wanglie* case (4), physicians recommended stopping mechanical ventilator treatments on the grounds that they were futile. In the 1994 *Baby K* case (5), physicians and ethics committees argued that certain treatments, such as a mechanical ventilator for an anencephalic patient, were "futile" and served "no therapeutic or palliative purpose and [were] medically unnecessary and inappropriate." In both of these cases, the judicial process came down squarely in favor of families being the final judge as to the appropriateness of continuing or stopping

treatment that might be medically futile. On the other hand, in the case of *Gilgunn v. Massachusetts General Hospital* (1995) (6), a court found in favor of physicians who argued that CPR need not be provided to a patient dying with multiple organ system failure, even if requested by the patient's family. (CPR is known to be ineffective in such circumstances if one defines effectiveness as discharge from the hospital.)

As these cases and others worked their way through the legal system, efforts were under way within the healing professions to define medical futility. Lundberg suggested that physicians should define medical futility and hospitals should develop guidelines for dealing with it (7). Numerous definitions were offered, including the concepts of physiologic, quantitative, and qualitative futility (8, 9). Some argued that the concept was too value laden to be used by the medical profession alone, and Lo argued that although the concept could sometimes be justified, it was "fraught with confusion, inconsistency, and controversy" (10). Others, however, suggested that just because the term was value laden did not mean it could not or should not be used by the profession. Schuster, for example, argued that the profession must distinguish between everything that can be done and everything that should be done (11).

As the debate over medical futility progressed in published reports and in courts of law, some institutions developed policies for dealing with medical futility. Some communities even developed voluntary community-wide guidelines (12). Finally, the American Medical Association (AMA) Council on Ethical and Judicial Affairs recommended guidelines for dealing with medical futility. These guidelines were similar to many already in use. Rather than offering a "one-size-fits-all" definition of futility, the guidelines recommended a process-based approach. The process involved the same counseling and deliberation that major ethics committees had been using for years, with attempts to transfer the patient to alternative providers if the disagreement could not be resolved. At the end of the process, if no resolution was achieved and no transfer to a willing provider could be arranged, the council noted that by ethical standards it was acceptable to halt futile treatments. Having said this, however, the council went on to note that "the legal ramifications of this course of action are uncertain."

It is unclear how effective such guidelines can be in the face of legal uncertainty. In my near 10-year experience with consults related to medical futility, many a physician, nurse, and even hospital ethics committee member felt that certain treatments in a given case were futile and should be stopped; however, few were willing to do so in the face of potential legal jeopardy.

THE TEXAS ADVANCE DIRECTIVES ACT OF 1999

The Texas Advance Directives Act combines several prior laws dealing with end-of-life decisions into a single statute and makes numerous changes of importance, including the provision of a new living will, new definitions of terminal and irreversible illness, and new witnessing requirements. For the purposes of this article, however, I will concentrate only on those provisions that affect the futility debate.

Advance directives in Texas clearly recognize that patients may use a directive to reject or request treatment in the face of terminal or irreversible illness. Surrogates acting on behalf of

incompetent patients may do the same. However, not all requests are necessarily granted. If there is a request for treatment that the treatment team feels is medically futile, an ethics consultation may be requested. Under the new law, the following process must occur if the treatment team and institution wish to take full advantage of the provisions of the law creating a legal safe harbor for them. These provisions are as follows:

1. The family must be given written information concerning hospital policy on the ethics consultation process.
2. The family must be given 48 hours' notice and be invited to participate in the ethics consultation process.
3. The ethics consultation process must provide a written report to the family of the findings of the ethics review process.
4. If the ethics consultation process fails to resolve the dispute, the hospital, working with the family, must try to arrange transfer to another provider physician and institution who are willing to give the treatment requested by the family and refused by the current treatment team.
5. If after 10 days, no such provider can be found, the hospital and physician may unilaterally withhold or withdraw the therapy that has been determined to be futile.
6. The party who disagrees may appeal to the relevant state court and ask the judge to grant an extension of time before treatment is withdrawn. This extension is to be granted only if the judge determines that there is a reasonable likelihood of finding a willing provider of the disputed treatment if more time is granted.
7. If either the family does not seek an extension or the judge fails to grant one, futile treatment may be unilaterally withdrawn by the treatment team with immunity from civil or criminal prosecution. (This is the "legal safe harbor" for physicians, institutions, and ethics committees, the first of its kind in the country.)

Several caveats about the statute are worth noting. It recognizes, as has the AMA Council on Legal and Judicial Affairs, that there is not a universally agreed-upon definition for medical futility and thus does not give a precise definition of futility. The statute does not ask the courts to make a determination of medical futility either, reserving that judgment to the medical profession checked by the process of consultation with an ethics or "medical" committee.

The statute recognizes that all institutions do not have ethics committees as yet—thus the provision for some other type of "medical committee." Those who wrote the new law believe that futility cases are most likely to occur, however, in large secondary and tertiary care hospitals, most of which now have some mechanism for dealing with ethical issues in medicine thanks to requirements of the Joint Commission on Accreditation of Healthcare Organizations.

The statute does not define all the rules by which an ethics committee must operate, other than ensuring that patients and families are informed of their rights and timing of participation, as well as the right to receive a written report at the end of the process.

Finally, in addition to creating for the first time in this country a "legal safe harbor" for resolving futility disputes, the statute creates a "moral safe harbor." It does this by providing a largely extrajudicial process of consultation with parties outside

the treatment team that has been used by many institutions over the past decade to help explore and resolve disagreements about medical futility when necessary.

THE LAW'S EFFECT ON THE CASE STUDY

How did the new law impact the case at the beginning of this article? Ethics consultation was first requested approximately 10 weeks before the new law went into effect. As in all consultations, the patient was examined and the chart extensively reviewed. Physicians, nurses, chaplains, and social workers caring for the patient were interviewed. Several face-to-face meetings were held with the patient's family. The ethics consultation team agreed with the treatment team that ongoing treatment other than comfort care was inappropriate and could be legitimately considered medically futile. For example, the following facts were noted:

- There is no good evidence in the medical literature that tube feedings in patients such as this resolve severe decubiti, nor do they resolve profound neurologic injury. In addition, there is little evidence demonstrating prolonged survival.
- There is good evidence that withholding artificial nutrition and hydration in dying patients will in some cases improve palliation, and this patient had ongoing pain.
- There is good evidence in the medical literature that CPR in cases such as this rarely leads to long-term survival with discharge from the hospital.
- The patient did not have any sort of advance directive. When reviewing his life values with his family, his elderly wife of several years was best able to express them, as well as her belief that he would not wish to be kept alive in his current circumstances.
- There was substantial concern that his adult daughter was experiencing direct secondary gain (financial) the longer he stayed alive.

Without going into all of the additional details of the ethics consultation, after approximately 2 weeks of working with the family and treatment team, the ethics consultation team recommended full withdrawal of treatment other than comfort care. The patient's daughter was unwilling to accept this recommendation, and the patient's wife, although legally empowered, refused to do so, saying that although she understood it to be the right decision for him, she had to continue to live in the same town as his biological family, and she would not cross them.

Still more than a month before the new law was to take effect, the attending physician was unwilling to withdraw treatment in the face of a daughter who was hostile to such action with its attendant potential for legal liability. The patient continued his slow downhill spiral even as "everything" was done.

As the September 1 beginning of the new Texas Advance Directives Act came into effect, the treatment team and ethics committee again attempted to achieve consent for withdrawal of treatment with a shift in goal to comfort care only. When such consent was again not forthcoming, the 10-day process was put into place. Neither the family nor the hospital social work department was able to identify an alternative physician and facility willing to provide the ongoing treatment that the Baylor treating physicians and ethics committee had deemed futile. A do-not-resuscitate order had been written, and other treatments

were continued. Before the 10-day time frame for unilateral withdrawal of treatment arrived, the patient died.

CONCLUSION

The new Texas Advance Directives Act brings many important benefits to patients, families, physicians, and medical institutions. These are discussed elsewhere in the medical literature. One is not mandated by law to follow the process outlined above; however, licensing authorities can penalize both physicians and nurses if the process is not followed. In addition, immunity from civil and criminal prosecution after ignoring the wishes of a surrogate health care decision-maker is offered only if the ethics consultation process is used.

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